

WSA 2002 Proposed Project Plan

Project Name:	Clinical Studies Data Management System
Objective:	To develop and implement an SAS-based data management system that provides for storage and analysis of raw data from all PM USA clinical trials.
Deliverable(s):	System
Reason for Doing this Work:	A system is needed to store raw clinical study data in-house in a secure and consistent format. Data contained in such a system will allow for inter- and intra-study exploratory analyses as well as complex meta-analytic research.
Program Area: (Select One)	<input type="checkbox"/> Cancer <input type="checkbox"/> CVD <input type="checkbox"/> COPD <input type="checkbox"/> Repro <input type="checkbox"/> ETS <input type="checkbox"/> Smoking Behavior <input checked="" type="checkbox"/> Clinical Testing <input type="checkbox"/> Communication <input type="checkbox"/> Acceptability Assessment <input type="checkbox"/> R.H. Evaluation <input type="checkbox"/> R.H. Guidance <input type="checkbox"/> Non-Clinical Testing <input type="checkbox"/> Non-Clinical Research
Project Leader:	Bettie Nelson

Tactics and Milestones:	Target Date:
Proposed scope of data management system defined by Human Studies group	06/30/02
Preliminary discussion held with IS to identify project process and user requirements	07/31/02
Project timeline determined with IS	?
Identification and procurement of external consultant resources (if required)	?
Pilot system implementation	?
Pilot system testing	?
Final system roll-out	?

Internal Resource Allocation (WSA, INBIFO)	External Resource Allocation (other PMUSA, external vendors)
Bettie Nelson, Qiwei Liang	IS